

April 21, 2022

Dear COVID-19 Vaccine Provider:

In August 2021 the U.S. Food and Drug Administration (FDA) amended the Emergency Use Authorizations (EUA) for both the Moderna and Pfizer COVID-19 vaccinations to allow third dose administration in individuals who are moderately or severely immunocompromised. The Advisory Committee on Immunization Practices voted to recommend a third dose of these vaccines for this population, as per below, and the Centers for Disease Control (CDC) Director officially adopted these recommendations.

Individuals eligible for a third dose include people with certain medical conditions or people receiving treatments that are associated with moderate to severe immune compromise such as:1

- Active treatment for solid tumor and hematologic malignancies.
- Receipt of solid-organ transplant and taking immunosuppressive therapy.
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy).
- Moderate or severe primary immunodeficiency (e.g., DiGeorge, Wiskott-Aldrich syndromes).
- Advanced or untreated HIV infection.
- Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

Verification of Eligibility:

- Testing to assess immune response and guide clinical care prior to third dose administration is not recommended.
- A doctor's note or prescription for a third dose is not required; self-attestation is all that is necessary to verify eligibility.

Dosage:

- The third dose is the same dosage as the first two dosages for both the Pfizer-BioNTech (30 mcg for those age 12 and older, 10 mcg from those age 5-11) and Moderna (100 mcg) vaccines.
- At this time, <u>CDC does not recommend</u> that immunocompromised persons who received Janssen vaccine receive an additional dose, but does recommend a booster dose at least 2 months after the primary dose (see Implementation Considerations below)

Age Criteria:

• The age criteria remain the same as for the initial series of the Pfizer (at least 5 years old) and Moderna (at least 18 years old) vaccines.

¹ Additional information about the level of immune suppression associated with a range of medical conditions and treatments can be found in general best practices for vaccination of people with altered immunocompetence, the CDC Yellow Book, and the Infectious Diseases Society of America policy statement, 2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host.

Timing:

- The third dose of either the Pfizer or Moderna vaccine should be administered at least 28 days following the second dose.
- Whenever possible, mRNA COVID-19 vaccination doses (including the primary series and an additional dose) should be given at least two weeks before initiation of immunosuppressive therapies.

Implementation Considerations and Boosters:

- For Pfizer and Moderna vaccines, the additional (third) dose should be the same mRNA vaccine as the primary series. However, the alternate mRNA vaccine can be used if the primary series one is not available.
- Immunocompromised persons who received Pfizer or Moderna 3rd doses should also receive a first booster dose 5 months later. This would therefore represent a 4th dose of vaccine. This booster is the same dose (30mcg) for Pfizer-BioNTech and half-dose (50 mcg) for the Moderna vaccine. NOTE: children aged 5-11 who are immunocompromised are not currently eligible for a booster (4th) dose of vaccine.
- CDC recommends that people aged 18+ who received Janssen vaccine as their initial vaccine, should get a first booster shot of either Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) in most situations, 2 months after the Janssen vaccine. **Note:** Although mRNA vaccines are preferred, Janssen COVID-19 vaccine may be considered in some situations.
- People 50 years and older should receive a second booster dose of either Pfizer-BioNTech or Moderna vaccine at least four months after first booster dose of a COVID-19 vaccine.
- Immunocompromised people 12 years and older should receive Pfizer-BioNTech vaccine at least four months after first booster dose of COVID-19 vaccine. Moderna vaccine can be administered to immunocompromised people 18 years and older at least four months after a first booster dose of COVID-19 vaccine.
- For persons 18–49 years of age that received Janssen vaccine as both their primary series dose and booster dose, should receive a second booster dose of either Pfizer-BioNTech vaccine or Moderna vaccine at least four months after the Janssen booster dose.

Storage and Handling:

Continue to follow all previous guidelines for the storage and administration of these vaccines.

Questions:

Please send any questions to COVIDVaccines@dhec.sc.gov.